

REPLY SUBMISSION ON STAKEHOLDER COMMENTS RELATING TO ROCHE DIAGNOSTICS, AND ROCHE DIABETES CARE

About Roche Diagnostics

Roche Diagnostics, a division of Roche Products (Pty) Ltd in South Africa, and it is involved in sales and marketing, installation, servicing, and supply chain of in-vitro diagnostic (IVD) products and medical devices hereby replies to submissions made by other stakeholders that relates to its business, products and pricing.

This submissions aims to provide further information so as to enable the Panel to place the comments made, within the correct context, and to correct inaccuracies found in such submissions.

Accu-chek strips

The BHF submission alleges differential pricing in relation to the provision of glucometer test strips.

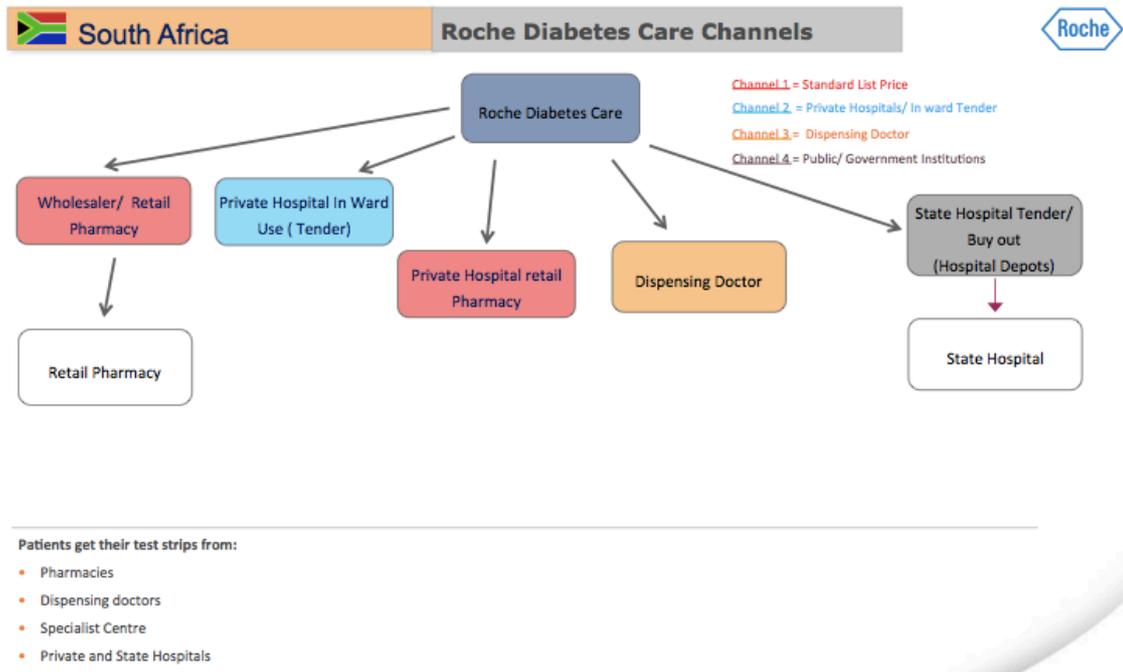
To understand this statement properly, the supply chain should be understood (fig. 1). Roche Diabetes Care provides products into four supply channels, viz.:

- Wholesale and retail pharmacy and Private hospital pharmacy;
- Private hospital ward;
- Dispensing doctor; and
- Public sector tenders / buy-outs.

Each channel fulfills a specific need and has a specific objectives. Diabetic patients who would have to routinely test their blood glucose levels to ensure that they take their medication correctly, would obtain their devices and the consumables from the retail pharmacy or hospital pharmacy (where hospital pharmacies do provide this) or their dispensing doctor. For this, Roche has a retail price list (Annexure "A"). In this sector Roche runs competition-law compliant discount deals, available to all in the market, a number of times a year.

Private hospital, in-ward, supplies relate to patients who have been hospitalized, and not all of them are diabetic, but would require, as part of their medical care, blood glucose monitoring. This is the channel that the BHF submission appear to refer to. Here there are two possible scenario's, i.e. the private hospital buys their strips from a wholesaler directly or into the hospital pharmacy, or the private hospital calls for a tender for the provision of test strips.

Fig 1:



Where the private hospital buys from the wholesaler directly, or buys through their hospital pharmacy, there could very well be a difference in cost, but such differences are within the market dynamics of those selling the products. Where a tender is called for, Roche, and other competitors, submit their proposals and details as is required by the specifications (including volume specifications) of the private sector tender, to the private hospital calling for bids. Furthermore, in order to prevent leakage of products, unauthorized sale, etc., the in-ward use strips are marked differently (fig 2.). A copy of the tender invitation is attached hereto as Annexure "B".

Fig. 2:



Any price differentials that result from these differences in approaches of private hospitals are therefore a function of how they operate, and their own efficiencies and business models. The same market principles function in relation to state / government tenders and buy-outs.

It has also become apparent that the prices provided in the BHF submission is not correct. The correct pricing is as follows, which corresponds with the specific supply chain and procurement method used by the customer.

In some hospitals Accu-Chek is not procured centrally, and some hospitals do use tender systems. The correct pricing is as follows:

Nappi List					
Nappi Name	Price	NHN	Netcare	Mediclinic	Life
Accu-Chek Active s	2.58	■	■	■	■
Correct Pricing	2.58	■	■	■	■

Point of care (POC)

The allegation is made that POC devices and POC tests are used in a manner that is perverse and/or increase costs. Roche supplies POC devices into the market, and can comment on this as follows:

The purpose of Point-of-care testing (POCT) is to bring a test result conveniently and immediately closer to the patient. This increases the likelihood that the patient, the doctor, and/or healthcare team will receive the results quicker, which allows for immediate clinical management decisions to be made. POCT is only effective if action is taken based on the test result offered.

The settings for POCT include decentralised sites (such as rural communities) which offers access to testing and treatment; emergency settings (such as ICU) where immediate test results are required to save a patient's life; and in patient self-testing environment.

POCT offers innovation that can potentially impact on the quality of care, but in this innovation are 2 reasons why a POCT result is often higher in cost than that produced by a centralised laboratory:

- i) the technology (both the device and the test strip / cartridge) is developed in such a way that it is as easy to use as possible, and by way of design, this often adds to the cost associated with POCT, and
- ii) that due to economies of scale far fewer tests are done at the POC as compared to a centralised laboratory (e.g. 10 tests per day versus 500 per day, respectively), and further the spreading of overhead costs of a facility over the test results, POCT costs more to generate a test result (if all costs considered).

These costs could be off-set with reference to the speed with which treatment and interventions can be instituted, and the lack of risk in terms of transportation, ease of sample collection and sample identification, etc.

The Department of Health has in the past produced a draft policy on POCT, which has, to the best of our knowledge, not been finalized.

Pricing in the diagnostic device supply field

In spite of a weakening Rand, and increases in inflation in aspects in which Roche has to deliver services to its customers (e.g. fuel and transportation increases), as well as remuneration of technical support staff, Roche were able to ensure that price increases on its products were kept within reasonable bounds. On average, price increases were as follows for the years 2010 – 2014:

	Average price increase to customers*	CPI	Exchange rate ¹ EUR = ZAR (% Change)
2010	2.8%	4.1%	9.7
2011	2.5%	5%	10.1 (4.1%)
2012	2.9%	5.8%	10.5 (4.5%)
2013	3.1%	5.8%	12.8 (21.4%)
2014	7.7%	6.1%	14.39 (12.4%)

*The above table does not consider price decreases as a for new tenders or contract renewals

Conclusion

If there are any other areas of concern raised by other stakeholders, or questions for clarification, Roche will be more than willing to assist.

Yours sincerely

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